Electronic Submissions @ FDA CDER

Barry Wheeler, Senior Technical Advisor

wheelerb@cder.fda.gov

ZAI AMELEX

An Information & Engineering Technology Company

8229 Boone Blvd., Suite 300
Vienna, Virginia 22182
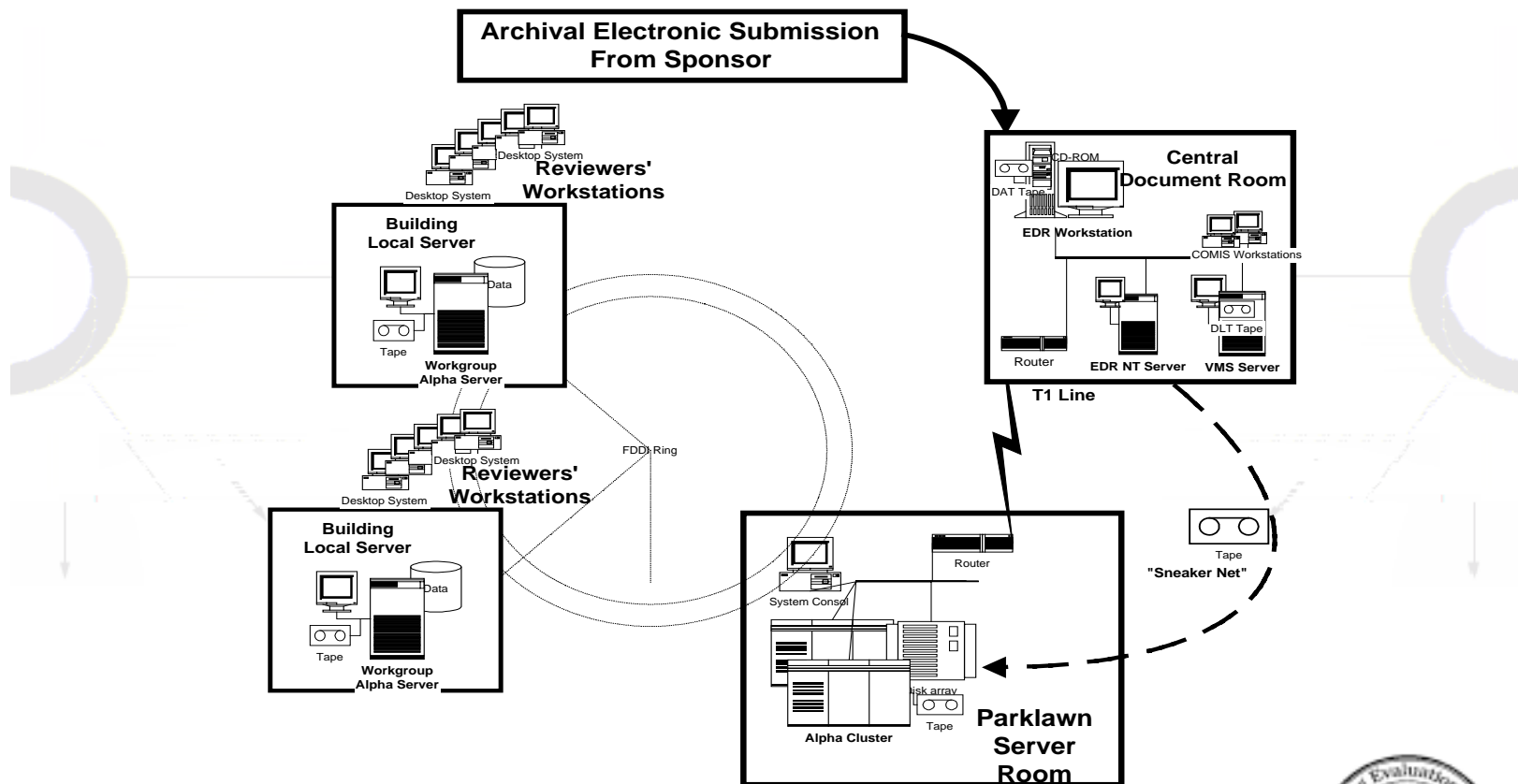(v) 703 883 0506 (f) 703 883 0526
http://www.zai-amelex.com

ZAI/AMELEX

An Information & Engineering Technology Company

- **Partners with FDA CDER for 8 Years**

- **Operate the CDER Document Rooms**

- **Designed, Implemented and Operate the Electronic Document Room**

    in accordance with CDER's Guidance

The CDER Electronic Document Room

Archival Electronic Submission From Sponsor

Reviewers' Workstations

Desktop System

Desktop System

Building Local Server

Data

Tape

Workgroup Alpha Server

Reviewers' Workstations

Desktop System

Desktop System

Building Local Server

Data

Tape

Workgroup Alpha Server

FDDI Ring

Central Document Room

CD-ROM

DAT Tape

EDR Workstation

COMIS Workstations

DLT Tape

Router

EDR NT Server

VMS Server

T1 Line

Tape

"Sneaker Net"

Router

System Console

Disk array

Tape

Alpha Cluster

Parklawn Server Room

Electronic Document Room

Increase Speed & Quality

Desktop Delivery w/Integrated

- – **Search & Access**
- – **Presentation**
- – **Navigation**
- – **Analytical Tools**
- – **Reporting**

Electronic
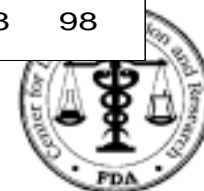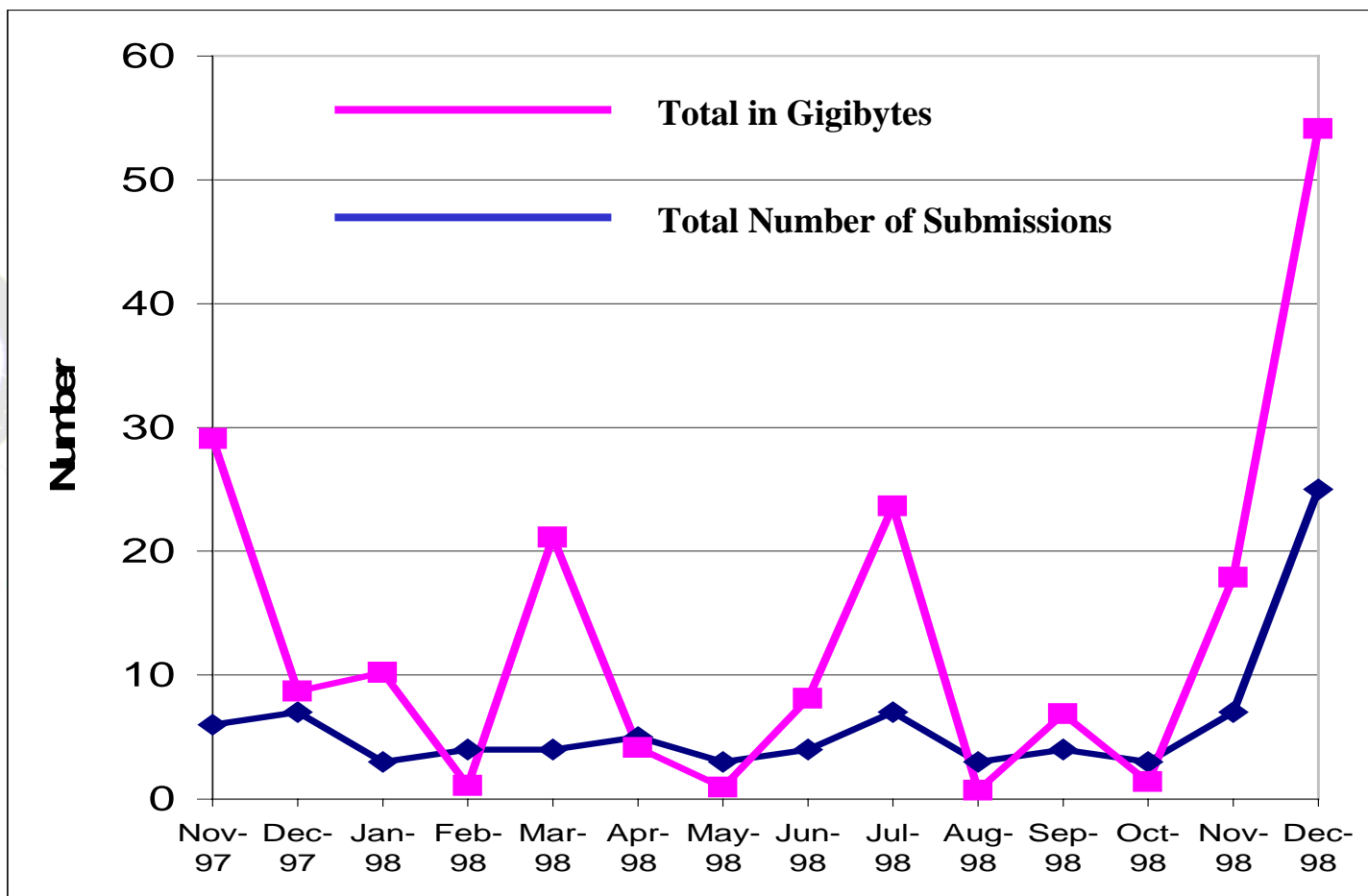**Document**
Room

Archival
Electronic Submissions

Require Independence from -

- **Specific Computer Hardware**
- **Specific Operating System and Version**
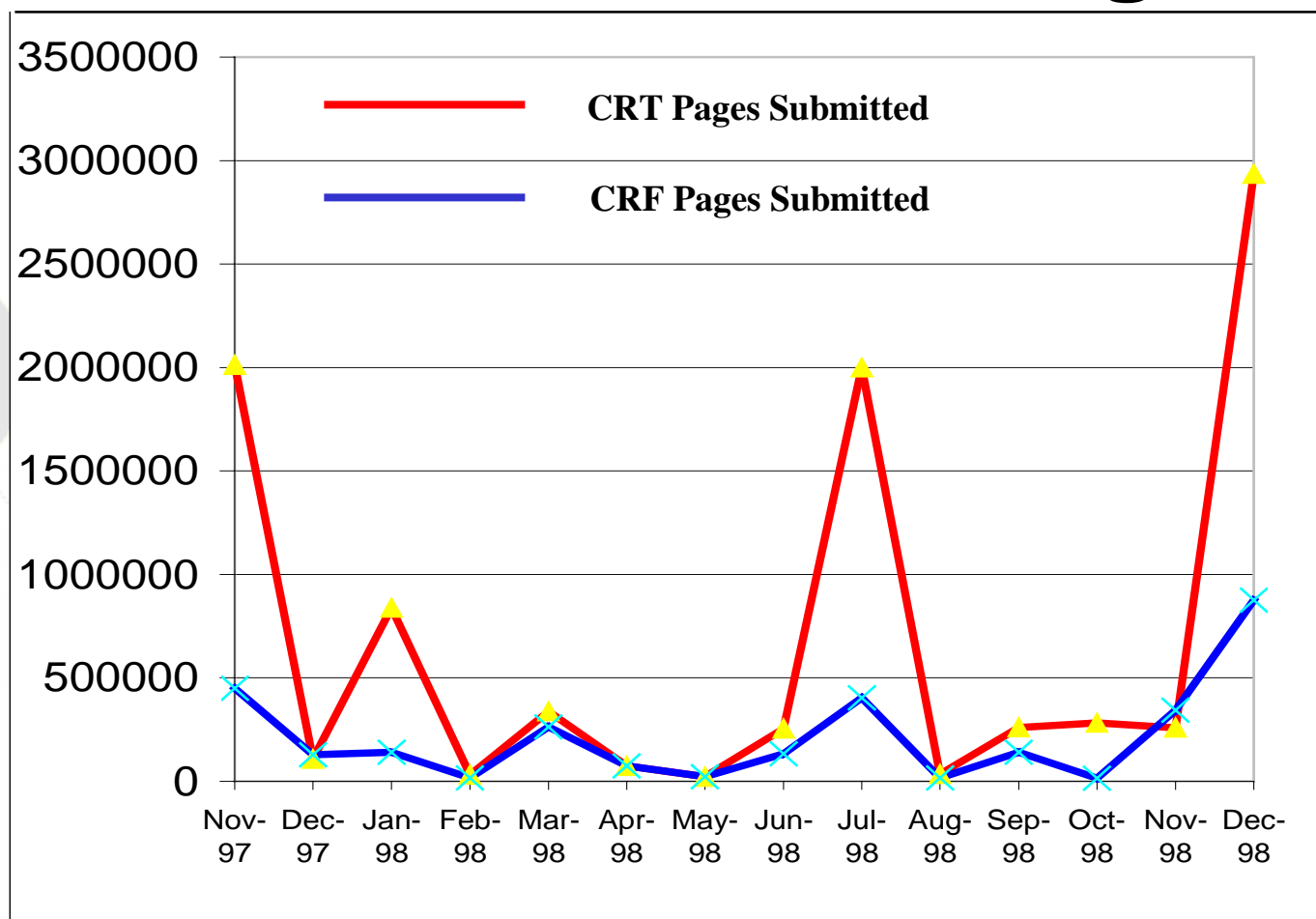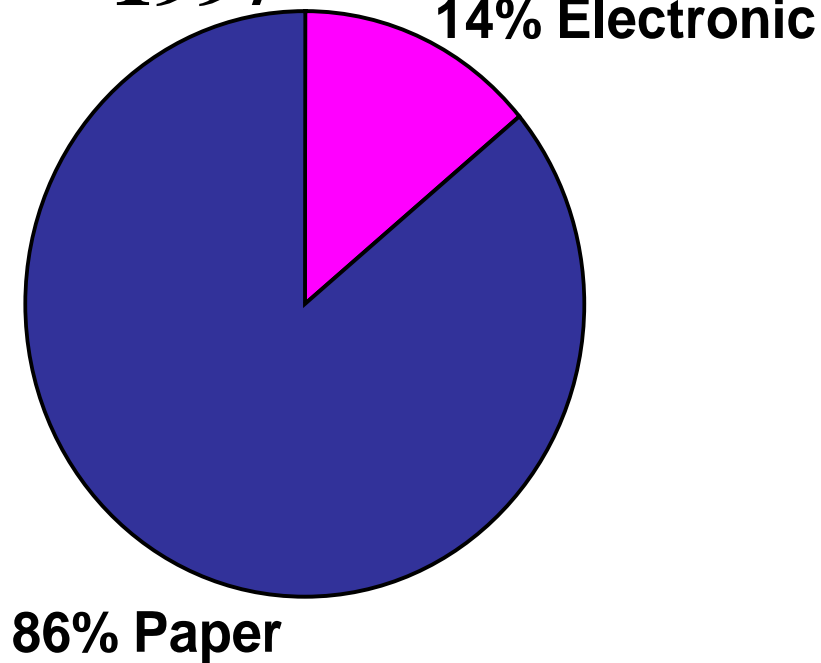- **Proprietary Application Software**

85 Electronic Submissions

Over 10 Million Pages

Electronic Document Room

Legend:
- **CRT Pages Submitted** (red)
- **CRF Pages Submitted** (blue)

Y-axis: 0, 500000, 1000000, 1500000, 2000000, 2500000, 3000000, 3500000

X-axis: Nov-97, Dec-97, Jan-98, Feb-98, Mar-98, Apr-98, May-98, Jun-98, Jul-98, Aug-98, Sep-98, Oct-98, Nov-98, Dec-98

Electronic Document Room

Paper Vs. Electronic -

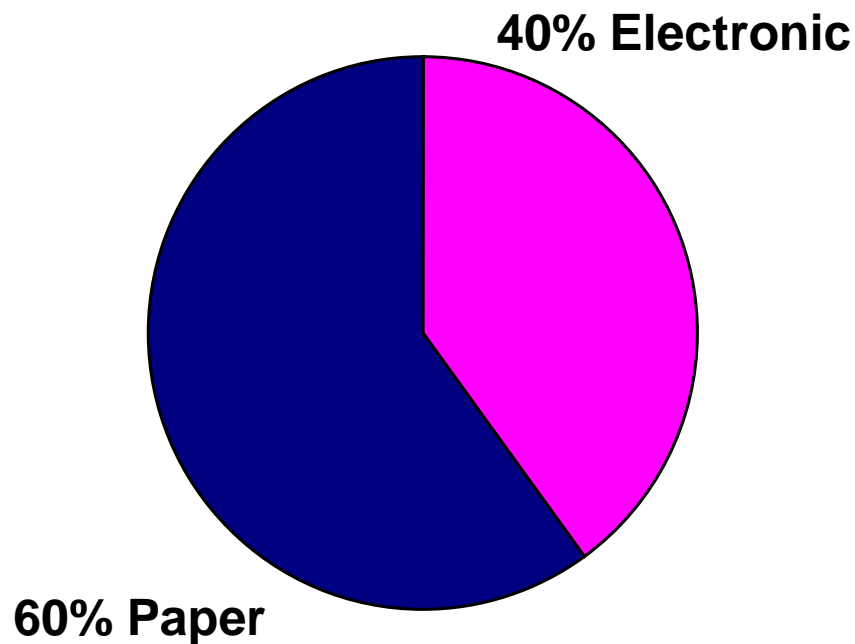## 1997

14% Electronic

86% Paper

1998

40% Electronic

60% Paper

EDR Technical Approach

- **Metadata Stored in CDER's Oracle Database**

- **Document Key of Six Fields**

- **Electronic Submission Linked to Specific Paper Document**

- **Web Server Locator/Access Services - Server-side Programming**

Electronic
Document
Room

Physical Processing

- **Locate Electronic Files & Separate from Paper**

- **Bind & Barcode _Transport Media_ (Not Archival)**

- **Core MetaData Entered into Oracle Database**

The EDR -

Cataloging Metadata

for Electronic Submissions

Electronic
Document
Room

- ## Map the submission
  - **Application >> Documents**
  - **Documents >> Item Subsections**
  - **Items >> Network Location**
- ## Search by Application Number and Trade Name

Electronic Document Room

Conformance Issues

The Conformance Checklist

- **The Guidance Document Online as an Acrobat *.pdf* Form**

- **Submission Review - Checkboxes and Comments on the Guidance Form**

- *Electronic Submissions Coordinator* **Can Provide Feedback to Sponsors**

Electronic Document Room

Network Mounting

CDER Personnel Can Control -

- **Building and Network Location**
- **Reviewer Access, and can**
- **Monitor E-sub Usage by CDER** *Username*

DIA FDA Electronic Submission Workshop

Data Integrity Issues

The EDR Staff Perform -

- **Directory and File Checks**
- **Binary Comparisons**
- **Online Presentation and Document Printout Checks**

Archival Tape Creation

- **Formats Archived Include**
  - **Adobe Acrobat (.pdf)**
  - **SAS Transport (.xpt)**
- **Currently NT Backup on 20/40 DLT Tapes**
- **Two Copies Barcoded and Stored**

DIA FDA Electronic Submission Workshop

Electronic
Document
Room

Electronic
Document
Room

Feedback   Help?

< EDR Home >

Application Documents
- NDA Search
- IND Search
- DMF Search

EDR Documents
- Library
- Checklist

DDMS Sources
- Orange Book
- DRLS

Related Sites
- CDERnet
- FDA/CDER

NDA Quick Search

0

⦿ NDA   Search

Welcome to the EDR
CDER's Electronic Document Room.

- **Reviewers can search for an application by entering the application number in the space to the left and using the search button.** This search will provide a list of the electronic Case Report Tabulations (CRTs) and Case Report Forms (CRFs) submitted for an original application, as well as for application amendments and supplements submitted electronically.
- **Reviewers may then select the desired Table of Contents** which will be automatically loaded into Adobe Acrobat for review.
- **Reviewers may use the _NDA Search_** View all documents of a specific NDA or view all documents of a specific Drug Trade Name.
- **Reviewers may also select additional services at left** as they become available.

The EDR is compatible with MS Internet Explorer 3.0 or better.

You must have
Get Acrobat® Reader
Adobe Acrobat 3.0

Best experienced with
Microsoft Internet Explorer
Click here to start.

activex

Powered by Microsoft
BackOffice

If you need help or would like more information you can
send FeedBack or call the EDR development team at (301) 827-5478,
They will be more than happy to help.

Done   Local intranet zone

Electronic
Document
Room

< EDR Home >

Application
  Documents
● NDA Search
● IND Search
● DMF Search

EDR
  Documents
● Library
● Doctrack
● Checklist

DDMS
  Sources
● Orange Book
● DRLS

Related
  Sites
● CDERnet
● FDA/CDER

Feedback   Help?

Search Results

Help

Application	Trade Name	Company Name
N987654	NEST Sample	CDER OIT Training

Type	Seq. Num.	Sup. Mod. Type	Stamp Date	App Location	Comments	Select Files
N			01-JUN-98	\\cdnta2\sample\n987654	OIT Training	Click here
N		BM	01-JUN-98	\\cdfda\common\software\classes\nest\n987654	OIT Training	Click here

Local intranet

PM LIVE

File   Edit   View   Favorites   Tools   Help

Address http://edr/   Go | Back   Forward   Stop   Refresh   Home   Search   Favorites   History | Links

Feedback   Help?

Electronic Document Room

< EDR Home >

Application Documents
● NDA Search
● IND Search
● DMF Search

EDR Documents
● Library
● Doctrack
● Checklist

DDMS Sources
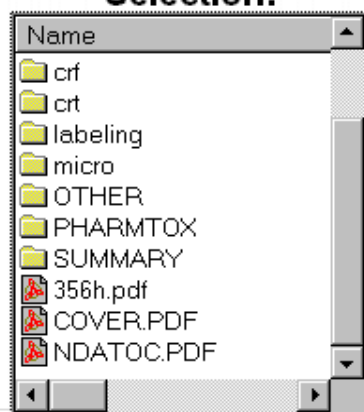● Orange Book
● DRLS

Related Sites
● CDERnet
● FDA/CDER

Application N 987654

Help ?

Selection:

Name
📁 crf
📁 crt
📁 labeling
📁 micro
📁 OTHER
📁 PHARMTOX
📁 SUMMARY
📄 356h.pdf
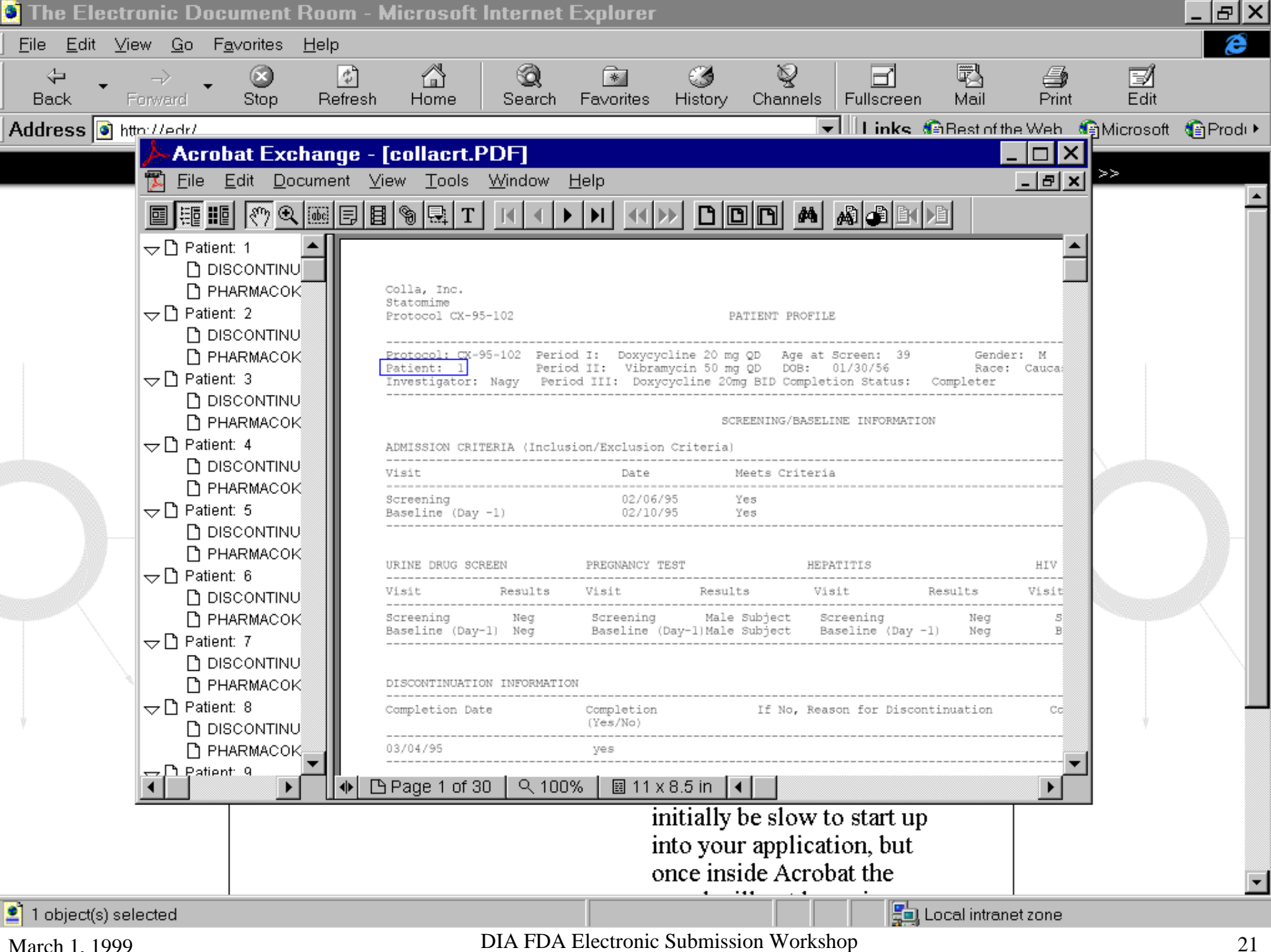📄 COVER.PDF
📄 NDATOC.PDF

**This application is located at:
\\cdnta2\sample**

Instructions:

1. Double click on one of the icons on the left labeled "Selection" to open your selected NDA.

2. The browser may ask you if you really want this content because if may contain viruses, but this data has been thoroughly checked by the EDR staff so click the "OK" button when it asks.

NOTE: This data is being transferred from the CDER network. It may initially be slow to start up into your application, but once inside Acrobat the speed will not be an issue. Much of this depends on how fast your computer is and how much RAM you have in your machine.

Local intranet

File Edit View Favorites Tools Help

Address 🔲 http://astrix/edrstaff/ ▼ ⮕Go | ⇦ Back | ⇨ Forward | Stop | Refresh | Home | Search | Favorites | History | » Links »

Electronic
Document
Room

Feedback 🖐   Help ❓

< Staff Home >

Add Doc.
● NDA
● IND
● DMF

Update Doc.
● NDA
● IND
● DMF

EDR Search
● NDA
● IND
● DMF

Miscellaneous
● Report
● Feedback

< EDR Home >
< Doctrack >

Insert Document Data
Help ❓

Appl_Type: N   Appl_No: [redacted]   Incoming_Doc_Type: P

Sup_Modification_Type: IN_DOC_TYPE_SEQ_NO: 001   Stamp Date: 10/15/96

Company Name: [redacted]

Drug Name: [redacted]

SEC_NO	FDA_FORM	MEDIA_TYPE	PATH	Comments
1	356H	E4	\\cdsedr1\N(	Screen Illustration
2	356H	E4	\\cdsedr1\N(	Screen Illustration
3	356H	P0	Located at the DDR	No Comments
4	356H	P0	Located at the DDR	No Comments
5	356H	P0	Located at the DDR	No Comments
6	356H	P0	Located at the DDR	No Comments
7	356H	P0	Located at the DDR	No Comments
8	356H	E4	\\cdsedr1\N(	Screen Illustration
9	356H	P0	Located at the DDR	No Comments
10	356H	E4	\\cdsedr1\N(	Screen Illustration
11	NONE	NA	Section Not Received	No Comments
12	356H	E4	\\cdsedr1\N(	Screen Illustration
13	356H	P0	Located at the DDR	No Comments
14	NONE	NA	Section Not Received	No Comments
15	356H	P0	Located at the DDR	No Comments

🖻   🖥 Local intranet

File Edit View Favorites Tools Help

Address http://edr/doctrack/

Links

[New Document | Update Document | Doctrack Reports | EDR | EDRStaff]

Welcome to the Document Submission Tracking System

Document Tracking System

◄ Change Doc. ►
1. Submission Detail
2. Media Inspect
3. Stage Document
4. Conformance
5. E-Mail
6. Net Load
7. Tape Backup
8. Cleanup
Document Report ►
◄ Main Page
Created By:
ZAI AMELEX

[0] **Search** Search for specific application document set.

Select an application from a list of all electronic submissions.

Reviewers can select "Change Doc" on the left to select a different submission or click "Main Page" to return here. To the left the Reviewers can select any one of the 8 steps a document must go through. Below the Reviewers can find detailed explanations for steps 1 - 8 on the left.

1) Submission Detail — An electronic submission is linked to a paper submission document for cataloging. After selecting a submission, users see detailed document description data from COMIS.

2) Media Inspect — EDR staff report on the e-submission transport media and data integrity.

3) Stage Document — Temporary location of the e-submission during the inspection, analysis and archiving process. Users may inspect the application at this location while reviewing the EDR staff reports.

4) Conformance — EDR Staff analysis of the electronic submission conformance to CDER Guidance specifications.

5) E-Mail — EDR Staff e-mail log during the analysys and archiving process.

6) Net Load — Location of the electronic submission for the review process and final data integrity report.

7) Tape Backup — EDR Staff archival tape creation logs.

8) Cleanup — EDR Staff summary report on final data entry, quality control review, and removal of the temporary data.

PM LIVE

File   Edit   View   Favorites   Tools   Help

Address http://edr/doctrack/   Go | Back   Forward   Stop   Refresh   Home   Search   Favorites   History | Links

Document Tracking System

[New Document | Update Document | Doctrack Reports | EDR | EDRStaff]

◄ Change Doc. ►

1. Submission Detail
2. Media Inspect
3. Stage Document
4. Conformance
5. E-Mail
6. Net Load
7. Tape Backup
8. Cleanup

Document Report ►
◄ Main Page
Created By:

ZAI
AMELEX

Document Info:

Appl_No: 0	Appl_Type: N	Document_ID: 1936596
Incoming_Doc_Type: N	In_Doc_Type_Seq_No: 0	Sup_Modification_Type:
Letter_Date: 14-Dec-1998	Stamp_Date: 14-Dec-1998	

Media Inspect

Document_ID   1936596   Integrity Check ☑   Date: 16-Dec-1998

Section	Size	Pages		Status	Dates:
1					
11	0	0		Hold Doc. ○	
12	0	0		Continue ◉	16-Dec-1998
Total	0	0			

All the 10 Diskettes with the blue folder returned to CDR1 on 16-Dec-1998. There are no files for the archive - this is an electronic review aid (ERA). The submissions is being sent to Division Document Room. Project Manager name not yet entered in ECH screen.

Submit   Reset

Previous Step   Next Step

Local intranet

File   Edit   View   Favorites   Tools   Help

Address http://edr/doctrack/   Go

Back   Forward   Stop   Refresh   Home   Search   Favorites   History   Links

Document Tracking System

Change Doc.
1. Submission Detail
2. Media Inspect
3. Stage Document
4. Conformance
5. E-Mail
6. Net Load
7. Tape Backup
8. Cleanup
Document Report
Main Page
Created By:
ZAI AMELEX

[New Document | Update Document | Doctrack Reports | EDR | EDRStaff]

Document Status

App_No.	Letter Date	In Doc Type	In Doc Type Seq No	Sup. mod. Type	1) Submission Detail	2) Media Inspect	3) Stage Document	4) Conformance	5) E-Mail	6) Net Load	7) Tape Backup	8) Cleanup
N0	20-Apr-1998	SE2	19	BS	●	●	●	●	●	●		●
N0	12-Feb-1998	SE8	18	BM	●		●	●	●			●
N0	16-Oct-1998	SE1	32		●	●	●	●	●	●	●	●
N0	6-May-1998	SE1	23		●	●	●	●	●	●	●	●
N0	23-Dec-1998	SE1	12		●	●	●	●	●	●	●	●
N0	13-Jan-1999	SE1	14	BM	●	●	●					
N0	22-Dec-1998	SE1	14		●	●	●	●	●	●	●	●
N0	27-Jul-1998	SE1	4		●	●	●	●	●	●	●	●
N0	24-Jul-1998	N	0	BZ	●	●	●	●			●	●
N0	18-Dec-1998	SE5	3		●	●	●	●	●	●		●
N0	20-Nov-1998	SE1	7	BM	●	●	●	●	●	●	●	●
N0	17-Sep-1998	SE1	7		●	●	●	●	●	●	●	●
N0	18-Sep-1998	SE8	15	BM	●	●	●	●		●		●
N0	5-Jun-1998	SE8	13		●	●	●	●		●		●
N0	26-Nov-1997	SE1	12		●	●	●	●		●	●	●
N0	30-Apr-1998	SE1	4	SU	●	●	●	●		●		●
N0____.	5-Dec-1997	SE1	4		●	●	●	●	●	●	●	●

Done   Local intranet

Issue -
Proprietary Information Security

- **CDER Network - Highly Secure, Double Firewall Intranet**

- **Physical Media for Data Transport and Submission**

- **Confidential Management of Proprietary Information**

Issue -
"Electronic Review Aids"

1. Electronic Archival Files

Designed to <u>Replace</u> paper

Submitted with Archival Copy

2. Review Aids

Designed to <u>Assist</u> Reviewers

Submitted with <u>Review</u> Copies

Prefer to Minimize Electronic Review Aids

Electronic
Document
Room

Initial Lessons Learned

- **Complex Document-based Records**
  **are very different from**

  Transactional Data-based Records

- **To Combine Both Documents and Data -**

  CDER's _**Hypertext Links**_ **between Acrobat Documents and SAS Datasets is One Workable Approach**

Electronic Document Room

Initial Lessons Learned

Manage the Details

In CDER's Example -

- **Follow the *Guidance* Closely !!!!**

- **Work with CDER's *Electronic Submission Coordinator***

- **Send Archival E-subs Directly to *The Central Document Room***

The Future of Electronic Submissions

New Document Types

at CDER

- **INDs, ANDAs, DMFs ...**
- **Await Experience with these Current First Steps**

Digital Signatures

Electronic Signatures in Lieu of Paper

- ## Docket 92s-0251

  – *Any Electronic Signature System That Complies With the Provisions of Part 11*

- ## Await a Robust Public Key Infrastructure